



# The Costa Rican Example

A large, faint circular graphic in the background. It contains the FDA logo in the center, surrounded by various icons representing food (apple, cow, fish), medicine (pill), and safety (radiation symbol).

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# The Situation

- New registration requirement for medical devices
- Not enough resources
- Backlog/Delays
- Unavailability of some devices --- risk to patient because of therapy not available

# The Opportunity

- Article 6 of WTO's Technical Barriers to Trade Agreement, and Article 17 of Decree 34482, provided the basis for recognition
- The Ministry issued agreement DAJ-RM-1151-08 to provide a procedure for such recognition
- At least 60% of devices imported came from the USA at the time
- The regulatory authority, FDA, is considered a strict regulatory agency under WHO's definition. FDA participated in the GHTF at the time (now in the IMDRF) and ICH and is currently member of PIC/S
- FDA's regional office opened in 2009 and was able to provide technical assistance to explain requirements and procedures



# The Results

- No need to review clinical data for safety and effectiveness for products that have already been shown safe and effective by FDA.
- Less documentation required for products that have been shown safe and effective.
- Backlog reduced for all products
- Better utilization of resources
- New therapies, not previously available to patients, now available to them with adequate protection to public health from unsafe devices

# Certificate to Foreign Government

- For Medical Devices that are shipped directly from USA to country of use.
- Product can be legally marketed in the USA.
- Establishments are in substantial compliance with applicable GMPs.
- Establishments are registered and products are listed with FDA.



# Additional Information:

[www.fda.gov](http://www.fda.gov)



Inspection Results Database:

<http://www.accessdata.fda.gov/scripts/inspsearch/>

Medical Device Inspections Database:

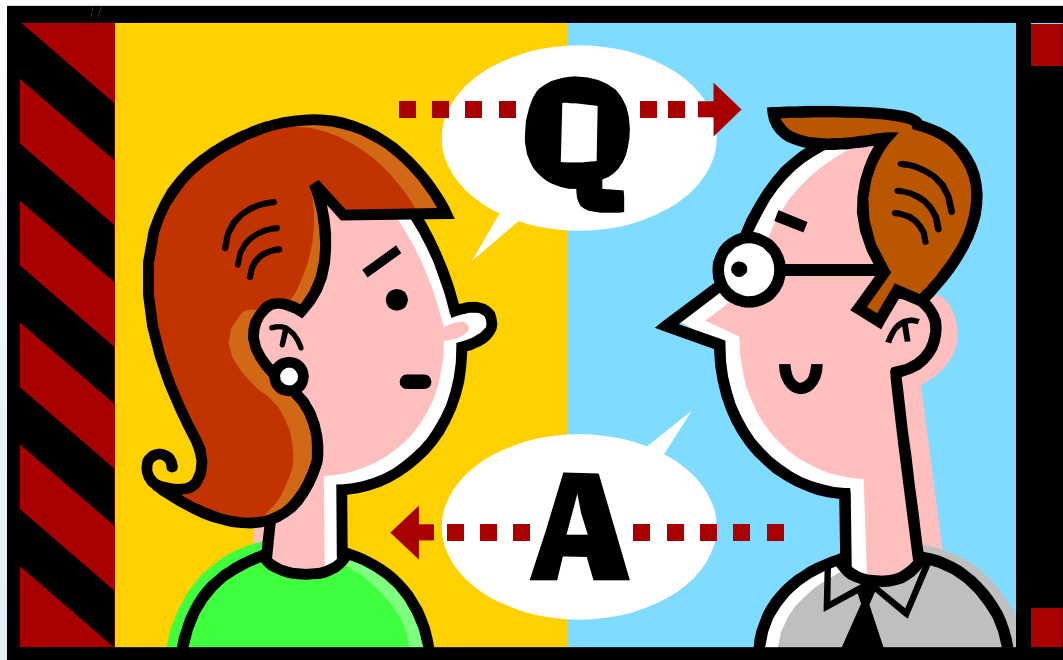
[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf  
TPLC/inspect.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/inspect.cfm)



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# Questions?



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